

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  RLL-404WO	<b>FOR FURTHER ACTION</b> <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No.  PCT/IB2004/002190	International filing date (day/month/year)  01/07/2004	(Earliest) Priority Date (day/month/year)  01/07/2003

Applicant

RANBAXY LABORATORIES LIMITED

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b.  With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2.  Certain claims were found unsearchable (See Box II).

3.  Unity of invention is lacking (see Box III).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. \_\_\_\_\_

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

b.  none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International Application No	PCT/IB2004/002190
------------------------------	-------------------

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/545 A61K9/14

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/44614 A (PARK JOON WOO ; CHUNG JONG KEUN (KR); KIM HAK HYOUNG (KR); LIM SANG HE) 10 September 1999 (1999-09-10) examples 1,3,5,7,9-14	1-28
X	WO 99/62559 A (SHERMAN BERNARD CHARLES) 9 December 1999 (1999-12-09) examples	1-28
X	WO 99/08683 A (SHERMAN BERNARD CHARLES) 25 February 1999 (1999-02-25) examples	1-28
Y	US 4 865 851 A (ELLIOTT LEONARD G ET AL) 12 September 1989 (1989-09-12) cited in the application column 2, line 52 - column 3, line 32 examples	1-28
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

14 December 2004

22/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.  
Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/IB2004/002190

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00/30647 A (RANEBURGER JOHANNES ; BIOCHEMIE GMBH (AT); JENNEWEIN HERWIG (AT)) 2 June 2000 (2000-06-02) page 4, line 9 - line 17 page 9, line 20 - line 31 page 12, line 3 - line 22 tables 1,2 -----	1-28
Y	WO 00/56286 A (SOMANI JITENDRA KRISHAN ; SEN HIMADRI (IN); BHUSHAN INDU (IN); RANBAXY) 28 September 2000 (2000-09-28) examples 1,2 -----	1-28

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

**Continuation of Box II.1**

Although claim 28 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

-----

**Continuation of Box II.1**

Claims Nos.: 28

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

-----

**Continuation of Box II.2**

Claims Nos.: 1,18 partly; 2

Present independent claim 1 relates to an extremely large number of possible dry powder compositions of cefuroxime axetil, namely all those comprising a granulate containing: 1) the active, 2) "a lubricant", and 3) "a glidant", with no restriction or limitation as to the nature of the lubricant and the glidant. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of said granulates, namely those wherein the lubricant is stearic acid and the glidant is colloidal SiO<sub>2</sub>. Other alternatives are not sufficiently disclosed in the application. It follows that claim 1 covers an area broader than justified by the extent of the disclosure and represents an undue generalisation. In particular, it is not shown/demonstrated in the application that the relevant technical problem (bioavailability) is also solved when the granulate comprises talc as glidant, or when it comprises other lubricants, as claimed in claims 5 and 7. In the present case, the claims so lack support and/or the application so lacks disclosure that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the subject-matter as defined above, i.e. claim 1 taken in combination with claim 16, in the sense of example 1.

It is the same for independent claim 18.

Claim 2 lacks clarity (Article 6 PCT). An attempt is made to define the composition by reference to the result to be achieved (bioavailability). Moreover, the definition used is a relative one established by comparison with a certain commercial composition. The lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2004/002190

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 28  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claim 28 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.  Claims Nos.: 1, 18 partly; 2  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/IB2004/002190

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9944614	A 10-09-1999	AT 232728 T AU 3277899 A CA 2322432 A1 DE 69905452 D1 EP 1066040 A1 JP 2002505290 T WO 9944614 A1		15-03-2003 20-09-1999 10-09-1999 27-03-2003 10-01-2001 19-02-2002 10-09-1999
WO 9962559	A 09-12-1999	CA 2239331 C AU 3807499 A WO 9962559 A1		30-11-1999 20-12-1999 09-12-1999
WO 9908683	A 25-02-1999	CA 2209868 A1 AT 213416 T AU 8847098 A WO 9908683 A1 DE 69803930 D1 DE 69803930 T2 EP 0996449 A1 ES 2172182 T3		15-02-1999 15-03-2002 08-03-1999 25-02-1999 28-03-2002 17-10-2002 03-05-2000 16-09-2002
US 4865851	A 12-09-1989	AT 393794 B AT 125988 A AU 607996 B2 AU 1615788 A BE 1000956 A5 CA 1328405 C CH 675357 A5 CN 88102851 A ,B CS 9104033 A3 CY 1600 A DE 3816464 A1 DK 263288 A ES 2009915 A6 FI 882253 A ,B, FR 2615101 A1 GB 2204792 A ,B GR 88100317 A ,B HK 106191 A HR 940557 A1 HU 47022 A2 IE 61693 B1 IL 86359 A IT 1219941 B JP 2049587 C JP 7078023 B JP 63303928 A KR 9509097 B1 LV 5726 A4 MX 11486 A NL 8801236 A ,B, NO 882123 A ,B, NZ 224598 A PH 26015 A PL 272429 A1 PT 87474 A ,B SE 466047 B SE 8801813 A		10-12-1991 15-06-1991 21-03-1991 17-11-1988 23-05-1989 12-04-1994 28-09-1990 21-12-1988 12-08-1992 03-04-1992 24-11-1988 15-11-1988 18-11-1988 23-11-1988 23-02-1989 03-01-1992 31-08-1997 30-01-1989 16-11-1994 15-11-1992 24-05-1990 10-05-1996 23-08-1995 12-12-1988 14-08-1995 20-04-1996 01-09-1993 01-12-1988 15-11-1988 29-08-1989 29-01-1992 20-02-1989 31-05-1989 09-12-1991 15-11-1988

**INTERNATIONAL SEARCH REPORT**
**Information on patent family members**
**International Application No**
**PCT/IB2004/002190**

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 4865851	A	SG	51491 G	23-08-1991
		SI	8810927 A , B	28-02-1997
		SK	277898 B6	11-07-1995
		SU	1837876 A3	30-08-1993
		YU	92788 A1	30-06-1990
		ZA	8803400 A	29-03-1989
		ZW	5988 A1	04-04-1990
-----				
WO 0030647	A 02-06-2000	AU	759517 B2	17-04-2003
		AU	1654400 A	13-06-2000
		BR	9915694 A	14-08-2001
		CA	2348876 A1	02-06-2000
		CN	1330546 T	09-01-2002
		CZ	20011845 A3	15-08-2001
		WO	0030647 A1	02-06-2000
		EP	1133298 A1	19-09-2001
		HU	0104412 A2	29-04-2002
		ID	28615 A	21-06-2001
		JP	2002530338 T	17-09-2002
		NO	20012526 A	23-05-2001
		NZ	511588 A	29-08-2003
		PL	348744 A1	03-06-2002
		SK	7162001 A3	08-10-2001
		TR	200101417 T2	21-11-2001
		US	6727243 B1	27-04-2004
		ZA	200103927 A	15-05-2002
-----				
WO 0056286	A 28-09-2000	AT	244560 T	15-07-2003
		AU	3184300 A	09-10-2000
		BR	0009177 A	22-01-2002
		CA	2366617 A1	28-09-2000
		EP	1165051 A1	02-01-2002
		ES	2202069 T3	01-04-2004
		HK	1043540 A1	24-12-2003
		WO	0056286 A1	28-09-2000
		PT	1165051 T	28-11-2003
		US	6346530 B1	12-02-2002
		US	6323193 B1	27-11-2001
		ZA	200107718 A	09-05-2002
		DE	60003796 D1	14-08-2003
		DE	60003796 T2	03-06-2004
		DK	1165051 T3	03-11-2003
-----				